

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

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Date of Deposit

Form PTO-1390-MOD (REV 10-96)		U. S. Department of Commerce Patent and Trademark Office	ATTORNEY'S DOCKET NUMBER 4-32609A
<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371</b>			U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/523,047
INTERNATIONAL APPLICATION NO. PCT/EP03/08719	INTERNATIONAL FILING DATE 6 August 2003 (06.08.03)	PRIORITY DATE CLAIMED	
TITLE OF INVENTION METHODS FOR THE TREATMENT OF DEMENTIA BASED ON APO E GENOTYPE			
APPLICANT(S) FOR DO/EO/US LANE ET AL.			

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau. (See Form PCT/IB/308)
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An executed Declaration and Power of Attorney (original or copy) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included.

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.  
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☒ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Sequence listing, paper copy

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
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The following fees are submitted:  21. <input type="checkbox"/> Basic national fee. . . . . \$  22. Examination Fee <input type="checkbox"/> If International preliminary examination report was prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4) . . . . . \$  <input type="checkbox"/> All other situations. . . . . \$  23. Search fee <input type="checkbox"/> If Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority. . . . . \$ <input type="checkbox"/> If International Search Report was prepared and provided to the Office. . . \$ <input type="checkbox"/> All other situations. . . . . \$					<b>CALCULATIONS</b> PTO USE ONLY	
<b>TOTAL OF 21, 22 AND 23 =</b>					\$	
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$ for each additional 50 sheets of paper or fraction thereof.						
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE			
- 100 =	/50 =		X \$			
Surcharge of <b>\$130.00</b> for furnishing the oath of declaration later than <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ 130.00		
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE			
Total claims	- 20 =		X \$			
Independent claims	- 3 =		X \$			
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$			
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$ 130.00</b>		
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).						
<b>SUBTOTAL =</b>				<b>\$ 130.00</b>		
Processing fee of \$ for furnishing the English translation later than <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$		
<b>TOTAL NATIONAL FEE =</b>				<b>\$ 130.00</b>		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$ per property				\$		
<b>TOTAL FEES ENCLOSED =</b>				<b>\$ 130.00</b>		
				Amount to be: refunded		\$
				charged		\$

- a. ☐ A check in the amount of \$\_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$130.00 to cover the above fees. A duplicate copy of this form is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

Send all correspondence to the address associated with Customer No. 001095, which is currently:

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080

*November 8, 2005*

*John T. Prince*  
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John T. Prince  
Attorney for Applicant  
Reg. No. 43,019  
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# RECEIVE

OCT 14 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/523,047	FIRST NAMED APPLICANT Roger M Lane	ATTY. DOCKET NO. DV 4-32609A
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INTERNATIONAL APPLICATION NO. PCT/EP03/08719
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I.A. FILING DATE 08/06/2003	PRIORITY DATE 08/07/2002
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001095  
 NOVARTIS  
 CORPORATE INTELLECTUAL PROPERTY  
 ONE HEALTH PLAZA 104/3  
 EAST HANOVER, NJ 07936-1080

JTP

CONFIRMATION NO. 7567

371 FORMALITIES LETTER



\*OC000000017072584\*

Date Mailed: 10/06/2005

## NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 02/02/2005
- Copy of the International Search Report filed on 02/02/2005
- Copy of IPE Report filed on 02/02/2005
- Preliminary Amendments filed on 02/02/2005
- Oath or Declaration filed on 02/02/2005
- U.S. Basic National Fees filed on 02/02/2005
- Priority Documents filed on 02/02/2005



The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

DOCKETED FOR: Dec 6, 2005

## SEQUENCE LISTING REQUIRED

- **\$130 Surcharge.**

- This application clearly fails to comply with the requirements of 37 CFR. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.** Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

KAREN R MCLEAN

Telephone: (703) 308-9140 EXT 214

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.

10/523,047

INTERNATIONAL APPLICATION NO.

PCT/EP03/08719

ATTY. DOCKET NO.

4-32609A

FORM PCT/DO/EO/905 (371 Formalities Notice)